

## SECTION 5: 510(k) SUMMARY

### AQUACEL® Hydrofiber® Wound Dressing

APR 16 2007

**Applicant:** ConvaTec  
A Division of E. R. Squibb & Sons, LLC  
200 Headquarters Park Drive  
Skillman, New Jersey 08558

**Contact:** Marilyn Konicky  
Associate Director, US and International Regulatory Affairs  
908-904-2541  
fax: 908-904-2235  
email: marilyn.konicky@bms.com

**Device:** AQUACEL® Hydrofiber® Wound Dressing

**Classification Name:** Dressing, Wound, Hydrophilic

**Product Code:** NAC

**Device Class:** Class I

**Substantially Equivalent Device:** MEPITEL® Non Adherent Silicone Dressing  
K984371

AQUACEL® dressing is a soft, sterile, non-woven pad or ribbon dressing composed of hydrocolloid fibers (sodium carboxymethylcellulose).

AQUACEL® dressing is indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions, lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional AQUACEL® dressing may be used for more serious wounds such as leg ulcers, pressure ulcers (Stages II-IV), diabetic ulcers, surgical wounds, donor sites, second degree burns, and wounds that are prone to bleeding. AQUACEL® may also be used for management of surgical or traumatic wounds that have been left open to heal by secondary intention.

AQUACEL® dressing is also indicated for the management of painful wounds. This management of painful wounds is due to the Hydrofiber® technology of AQUACEL® dressing, which forms a clear, cool gel on contact with wound exudate. The gel also assists in the non-traumatic removal of the dressing without damaging newly formed tissue.

ConvaTec has conducted three prospective, controlled, randomized studies with AQUACEL® dressings and one similar study with AQUACEL® Ag dressings and has reviewed the literature for published reports. Data from these four ConvaTec studies and from three published studies cover various aspects of wound management including the level of pain while the dressing is in situ, and the measurement of pain during dressing changes. These studies support the management of painful wounds indication. In addition, the studies also support the claim that the gelling action of Hydrofiber® technology in the dressings reduce wound pain while the dressing is in situ, and helps reduce the pain and trauma upon dressing removal.

Regardless of the dressings used (AQUACEL® or AQUACEL® Ag) in each study, these studies are mutually supportive for each product for the management of painful wounds indication because both dressings incorporate Hydrofiber® technology. The only difference between the two dressings is the ionic silver in AQUACEL® Ag, which is included for microbial protection.

Hydrofiber® technology has a gelling action that absorbs and retains wound exudate. Unlike alginate dressings and gauze, the gelling fibers in dressings with Hydrofiber® technology absorb fluid within the structure of the fibers, thus forming a cohesive gel. The gel forms a moist wound environment that provides patient comfort during wear and ease of removal during dressing changes.

For AQUACEL® dressings, three clinical prospective, comparative, randomized studies conducted by ConvaTec are summarized in this section. Two studies compared the performance of the product in the management of leg ulcers and one study evaluated the dressing performance in the management of pressure ulcers. In addition to these clinical studies, three published studies from peer review journals are summarized, which provide data from prospective, randomized, controlled studies in patients with acute surgical wounds, split-thickness donor sites and partial-thickness burns.

#### Clinical Performance Studies

One study involved the management of moderately to heavily exudating leg ulcers. Forty-four patients were recruited and patients remained in the study for a maximum period of 6 weeks, or to healing, or when the level of exudates decreased to "low." Of the 44 patients recruited, 21 were managed with AQUACEL® and 23 with Kaltostat® Dressings. The mean age was 68.1 years. The etiology was venous for 82% of patients and for 89% of the patients, the ulcer depth was shallow. The median duration of the ulcers was 10 months. No pain, mild pain and moderate pain on dressing change was rated by 76%, 20% and 3% of AQUACEL® patients, respectively. For the Kaltostat treated patients, the results were 83% reporting no pain, 13% reporting mild pain and 4% reporting moderate pain.

Another study was a multicenter study in the management of leg ulcers. Twenty patients were managed with AQUACEL® dressings and 20 with an alginate dressing. The majority of the patients enrolled were male (80%) and the average age was 63 years. The performance of both dressings was compared including pain upon dressing removal. The results are based on 269 dressing changes for AQUACEL® and 227 dressing changes for the alginate dressing. For the AQUACEL® group, 65% of patients reported no pain on dressing removal, 16% reported mild pain and 3.4 % reported moderate pain versus 62% reporting no pain, 14% reporting mild pain and 4% reporting moderate pain on removal of the alginate dressing.

The third study evaluated the performance of AQUACEL® by comparing it to a moist saline dressing in patients with pressure ulcers. Eighty-five patients with moderately or heavily exudating Stage III or IV pressure ulcers were enrolled. The AQUACEL® dressing group consisted of 43 patients and a total of 536 dressing changes while the gauze group consisted of 42 subjects and a total of 500 dressing changes. The duration of the study was a minimum of 10 days and a maximum of 28 days. For pain on removal, the dressing was rated as excellent or good by 54% and 28% of the patients treated with AQUACEL®, respectively. Only 7% of patients treated with the gauze dressing rated the dressing as excellent while 17% rated the gauze dressing as good for pain on removal.

#### Published Reports

Foster, et al conducted a study comparing AQUACEL® and an alginate dressing in patients with acute surgical wounds. One hundred patients were randomized prior to surgery to receive either AQUACEL® or the alginate dressing. No or mild pain was experienced at the first dressing change by 92% of the AQUACEL® managed patients and 80% of the alginate managed patients. On postoperative day 7, 84% of the AQUACEL® patients were pain free while only 58% of the alginate patients were pain free.

Barnea, et al published results of a prospective, comparative study in the management of split-thickness skin graft donor sites. Twenty-three (23) adult patients were treated with both AQUACEL® and paraffin gauze with half the donor site covered with AQUACEL® and the other half with paraffin gauze. Local pain was assessed using an analogue scale and pain was measured on days 3, 7, 10 to 14, and when the dressing fell off. Pain scores at all evaluation points were significantly lower for AQUACEL® compared to paraffin gauze with the p values ranging from 0.0001 on day 1 to 0.03 on day 15. The authors note that AQUACEL® dressing forms a highly absorbent gel, which allows ease of removal, reduces trauma during dressing changes and provides a moist wound/dressing interface that protects nerve endings.

In a published report of a prospective study in patients with partial-thickness burns by Kogan, et al, patients (1.5 to 41 years) were treated with either AQUACEL® (n=11) or

April 5, 2007

with silver sulphadiazine (n=11). Pain was assessed during dressing change and a half-hour later using visual analogue scales for adults and children over the age of 7 years, and for non-verbal children, pain was assessed by observation of behavior. On days 1 and 2, pain intensity was high (8-9 points) in children and adults in both groups. At the half-hour assessment, pain was reduced to 6.1 in the AQUACEL® group and 6.9 in the silver sulphadiazine group. On day 3, pain intensity began to decline and by day 5, pain intensity was about 7-8 points in both groups and at the half-hour assessment, pain intensity was 5.2 for the AQUACEL® group and 5.6 for the silver sulphadiazine group. The authors concluded that the pain relief effect of AQUACEL® was superior to silver sulphadiazine.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

ConvaTec  
% Ms. Marilyn Konicky  
Associate Director, Regulatory Affairs  
200 Headquarters Park Drive  
Skillman, New Jersey 08558

APR 16 2007

Re: K063271  
Trade/Device Name: AQUACEL® Hydrofiber® Wound Dressing  
AQUACEL® Ag with Hydrofiber®  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: April 5, 2007  
Received: April 10, 2007

Dear Ms. Konicky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

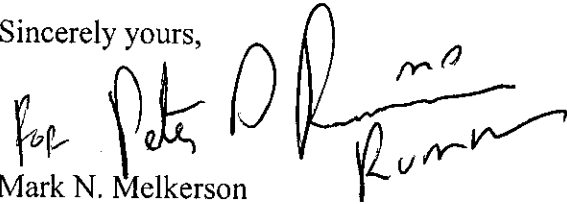
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Marilyn Konicky

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Peter D. Rumm", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**SECTION 4: INDICATIONS FOR USE STATEMENT**

**510(K) Number (if known):** K063271

**Device names:** AQUACEL® Hydrofiber® Wound Dressing

**Indications for Use:**

*For Over - the - Counter use, Aquacel Hydrofiber Wound Dressing may be used for:*

- abrasions
- lacerations
- minor cuts
- minor scalds and burns

*Under the supervision of a health care professional, Aquacel may be used for the management of:*

- leg ulcers, pressure ulcers (Stage II-IV) and diabetic ulcers
- surgical wounds (post-operative, donor sites, dermatological)
- second degree burns

*Aquacel may also be used for:*

- management of surgical or traumatic wounds that have been left to heal by secondary intention.
- local management of wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided, donor sites, and traumatic wounds.
- the management of painful wounds<sup>1</sup>

**Prescription Use**   X  

**AND/OR**

**Over-the-Counter Use**   X  

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

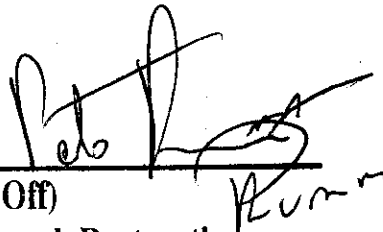
<sup>1</sup> New Indication, not previously cleared under K982116

April 5, 2007

**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED**

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number 11063271



**SECTION 4: INDICATIONS FOR USE STATEMENT, CONTINUED**

**510(K) Number (if known):** K063271

**Device names:** AQUACEL® Ag with Hydrofiber®  
Silver Impregnated Antimicrobial Dressing

**Indications for Use:**

*For over-the-counter use, Aquacel-Ag may be used for:*

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

*Under the supervision of a health care professional, Aquacel-Ag may be used for the management of:*

- wounds as an effective barrier to bacterial penetration to help reduce infection;
- partial thickness (second degree) burns;
- diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed aetiology) and pressure ulcers/sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided;
- oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma.
- **the management of painful wounds<sup>2</sup>**

Aquacel Ag may be used on minimally exuding, non-exuding and dry wounds, as stated in the **DIRECTIONS FOR USE**.

Prescription Use   X   AND/OR Over-the-Counter Use   X    
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

---

<sup>2</sup> New Indication, not previously cleared under K013814

April 5, 2007

**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED**

---

**Concurrence of CDRH, Office of Device Evaluation (ODE)**